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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,936	04/14/2004	Vahid Saadat	USGINZ00700	7289

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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,936	Applicant(s) SAADAT ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 16-19, 23, 24, 26, 27, 29-34, 36-38 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16-19, 23, 24, 26, 27, 29-34, 36-38 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/8</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on July 14, 2008, amended claims 1 and 31 are acknowledged. The current rejections of the claims are *withdrawn*. The following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 16-19, 23-24, 26-27, 29-34, 36-38 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0096502 to Khalili in view of U.S. Patent No. 5,251,611 to Zehel et al.

In regards to claim 1, Khalili discloses an apparatus for obtaining endoluminal access, the apparatus comprising: a flexible elongate body 4 having a working axis and a distal region 18, the elongate body configured for insertion within a body lumen (see paragraphs 0045 and 0057); at least two working lumens 12, 14, 16 extending through the flexible elongate body; at least one articulating element 38 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by at least one linkage member 36, 34 and at least one hinge 30, 28, wherein the articulating element is configured to articulate from an in-line position to an off-axis position relative to the working axis of the elongate body (see Figs. 1a-d and

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paragraphs 0009-0012). **In regard to claim 31**, Khalili discloses a method of passing a diagnostic or therapeutic tool through a working lumen provided in the elongate body (see Fig. 5 and paragraphs 0050 and 0063-0064). Khalili disclose that the elongated body the elongated body 4 may be rigid, flexible, or partially flexible depending on the particular application. For example, for laprascopic surgery, it may be desirable to have a rigid elongated body. For insertion into a patient's stomach, the distal section 6 of the elongated body may be rigid, and the proximal section 8 may be flexible so that it can be easily inserted down the esophagus (see paragraph 0048). However, Khalili is silent with respect to the elongate body comprising a plurality of links and at least one tensioning wire whereby the elongate body has a first, substantially flexible state and a second, substantially rigid state. Zehel et al. teach of an analogous apparatus wherein a preferred inner flexible conduit 10 consisting of a plurality of generally cylindrically shaped beads or segments 19 strung on flexible cables 20 passing slidably through the segments 19 by way of a channel 21 bored therein, as best seen in FIG. 3.

Alternatively, the cables 20 may be slidably disposed within the segments 19 by means of loops, grooves, or any other means slidably retaining the cables 20 at their radial position with respect to the segment, whether the cable is relaxed or flexed (see Figs. 1-3 and Col. 6, Line 40- - Col. 7, Line 50). Furthermore, Zehel et al. teach that the device thus can be an add-on device for an existing endoscope or the stiffening feature may be included in the basic endoscope and one or more segmented concentric devices of the invention may be used around the endoscope (see Col. 10, Lines 20-37). It would have been obvious to one skilled in the art to at the time the invention was made to

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construct the elongate body of Khalili with a plurality of links and a tensioning wire to create a rigid state in order to provide a stable platform for the deployment of exploratory instruments and thus minimize surgical trauma to the patient and decrease the complexity involved in operating the surgical instruments as taught by Zehel et al.

In regards to claims 2 and 32, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises a visualization element 110 configured to image within a body lumen (see Fig. 7a and paragraph 0066).

In regards to claim 3, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises the distal region of a working lumen extending through the elongate body (see Figs. 1a-d and paragraph 0050).

In regards to claims 4 and 37, Khalili discloses an apparatus for obtaining endoluminal access, wherein the apparatus has a delivery configuration in which the articulating element is aligned with or adjacent to the working axis of the elongate body, and a deployed configuration wherein the articulating element is articulated off-axis from the working axis of the elongate body (see Figs. 1a-d and paragraphs 0009-0016).

In regards to claim 5, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises at least two articulating elements (see Fig. 1c and paragraph 0065).

In regards to claims 6-7, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements are configured for independent off-axis articulation or coordinated off-axis articulation (see paragraphs 0050 and 0054).

In regards to claims 8-9, 33 and 41, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization (see paragraph 0066).

In regards to claims 16-17 and 34, Khalili discloses an apparatus for obtaining endoluminal access, wherein off-axis articulation of the articulating element is configured to expose a distal opening of the working lumen (see Fig. 1b).

In regards to claims 18, 38 and 40, Khalili discloses an apparatus for obtaining endoluminal access, wherein the distal opening is covered by the articulating element in the deliver configuration as the articulating element is capable multiple degrees of freedom, thus allowing manipulation of the element in and out of line with the working axis as desired (see Figs. 1a, 8 and paragraphs 0013, 0071).

In regards to claim 19, Khalili discloses an apparatus for obtaining endoluminal access, further comprising a visualization element and wherein off-axis articulation of the articulating element is configured to expose the visualization element (see Figs. 1a-d and 8).

In regards to claim 23, Khalili discloses an apparatus for obtaining endoluminal access further comprising a housing configured to couple the articulating element to the elongate body and to facilitate articulation of the articulating element (see Figs. 3).

In regards to claim 24, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element is supported on the body by a pair of pivoting links (see Figs. 8 and 9a-b).

In regards to claims 26-27 and 42-43, Khalili on discloses an apparatus for obtaining endoluminal access, wherein the elongate body is steerable and may be rigidizable (see paragraphs 0009-0016, 0044-0045, 0048 and 0084-0087).

In regards to claim 29, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises a diagnostic tool (see paragraph 0046 and 0066).

In regards to claim 30, Khalili discloses an apparatus for obtaining endoluminal access, further comprising an atraumatic tip 60 (see paragraph 0057).

In regards to claim 36, Khalili discloses a method for obtaining endoluminal access, further comprising injecting or withdrawing fluid through the working lumen (see paragraph 0068).

Response to Arguments

Applicant's arguments with respect to claims 1-9, 16-19, 23-24, 26-27, 29-34, 36-38 and 40-43 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739

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